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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,931	12/18/2001	Timothy A. J. Haystead	3263.1000-000	2591

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,931

Applicant(s)

HAYSTEAD ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant's election without traverse of Group II, claims 39-69 in Paper No.8 is acknowledged.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The date of signature for inventor Timothy Haystead is missing.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).

5. Claims 39-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The functional limitations recited on lines 4-8 of claim 39 are indefinite since claim 39 does not positively recite that a compound of the proteome is bound to the ligands on the array of affinity elements. Therefore, the elution of the bound compound in these functional limitations

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is vague and unclear. The functional limitations on lines 4-8 of claim 39 do not further limit the structural components of the apparatus, and are not given patentable weight.

On line 2 of claim 44, the phrase "the flow of liquid from the tube sheet through the affinity array" lacks antecedent basis.

On lines 1 and 4 of claim 56, the phrase "the collection tubes" lacks antecedent basis since claim 56 does not ultimately depend from claim 43, which positively recites the collection tubes. Similarly, on lines 2-3 of claim 56, the phrase "the centrifuge basket" lacks antecedent basis.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al (US 2002/0001803, submitted in the Information Disclosure Statement filed on June 30, 2003).

Smith et al teach of an apparatus for conducting chemical or biochemical reactions, such as hybridization reactions between a biological probe and a target analyte. The apparatus comprises a solid array containing surface-bound molecular probes. The array can be an oligonucleotide array, which contains a pattern of oligonucleotides that are bound to a substrate surface within a reaction area and arranged in a spatially defined and physically addressable manner. The array of probes can be arranged on a cover plate 36, which is used to cover a housing 44 having a plurality of recesses 32 therein. Each of the recesses 32 contains a sample to be tested. When the cover 36 is placed over the housing 44, enclosed chambers are formed, wherein a different solid phase chemical or biochemical reaction is carried out. The array of enclosed chambers can be placed onto a centrifugation device 47 depicted in Figure 6 of Smith et al to subject the array to a centrifugal force. The centrifugation device 47 contains an upper surface 49 of a rotor 48 that has a radially positioned arm 54. Attached to one end of the arm is a swing basket or mixing device 10, into which the array of enclosed chambers is placed. During centrifugation, the control means 58 of the rotor causes the swing basket or mixing device 10 to be tilted around a hinge so as to rotate about the hinge, and cause the mixing of the probe material with the sample in each recess 32 of the array. See paragraph nos. 0054-055 in column 5, and figures 4-6 in Smith et al. Since the limitations concerning the release of a compound of a proteome attached to a ligand on the array as a component of an eluate on lines 4-8 of claim 39 are merely functional in nature, these limitations are not given patentable weight in the apparatus

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claim, and the apparatus taught by Smith et al anticipates claims 39-42 for the reasons given above.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 39-44, 50-53 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over either reference to Haystead (WO 00/63694 or the article from Current Drug Discovery, both submitted in the Information Disclosure Statement filed on December 18, 2001) in view of Burbaum et al.

Both references to Haystead teach of a method and apparatus for proteome mining or screening for the discovery of new drugs. The apparatus comprises an ATP affinity array apparatus, which comprises an array of columns having therein an immobilized compound library. The columns contain a particulate solid support therein, such as sepharose or agarose beads. The individual components of the compound library are bound to the supports. Protein

members of a preselected proteome are fed into the columns for binding between the proteins and the immobilized probes. Any unbound protein is washed from the columns with a buffered solution. After the supports are washed with buffer, the remaining bound proteins are released from the solid supports by contacting the bound proteins with one or more individual members of the compound library or with the use of a chaotropic agent. The released proteins are then identified by protein sequencing or mass spectrometry. Haystead teaches that the solutions/suspensions are allowed to percolate through the columns of the array based on gravity, or additional force can be applied to speed the flow of the eluate through the columns, such as centrifugal force by spinning the columns in a centrifuge to enhance the flow through the columns. See lines 15-23 on page 15 of WO 00/63694, and see figure 2 in the Haystead article. Both references to Haystead fail to teach of a means for centrifuging the array of columns so as to transfer fluids from protein sample-containing tubes to the columns, and for transferring the separated bound proteins from the columns to collection tubes.

Burbaum et al teach of an apparatus for performing high throughput parallel separation, filtration or screening assays involved with drug discovery programs. The apparatus employs centrifugation to achieve the transfer of fluids from one multi-sample array or plate to another. The apparatus comprises aligned multi-well arrays that are held together by special posts. The aligned arrays are then placed into a swing basket 220 of a centrifuge, and rotated to affect the desired separation and transfer of solutions between the aligned wells of different plates. Figure 6 of Burbaum et al depicts a swinging bucket plate centrifuge 650, in which the aligned arrays are placed. A centrifugal force is applied that causes the arrays to rotate about a hinge of the bucket.

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Based upon a combination of the references to Haystead and Burbaum et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the apparatus taught by Haystead with a means for applying a centrifugal force to the columns of the array so as to transfer fluids from protein sample-containing tubes to the columns, and for transferring the separated bound proteins from the columns to collection tubes, since Haystead provides the suggestion to centrifuge the columns in order to enhance the flow of fluid therethrough, and since Burbaum et al teach that the use of centrifugal force for the transfer of fluids between multi-sample arrays is known in the art of high throughput screening for potential drugs, which is the type of assay disclosed by Haystead for the high throughput screening of proteomes.

12. Claims 45-49, 54-58 and 62-69 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a tube sheet for use with an array of columns, wherein the tube sheet has orifices therein for directing a wash solution through the columns. In addition, none of the prior art of record teaches or fairly suggests the use of a nano-needle array in conjunction with an array of columns containing bound proteins therein for the collection of the released proteins and the transfer of the proteins to a mass spectrometer for analysis.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Holzman et al. who teach of a centrifuge-enhanced method for determining ligand/target affinity.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 25, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1700~~ 1700